

DEFENDANT
EXHIBIT
CAH-WV-00026



Document Title	Issue Date	Document Number	
ON-SITE INVESTIGATIONS	11/05/09	PDQRA-CAD-C008	
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Pharmaceutical Distribution	12/22/08	[PAGE * MERGEFORM AT \ PAGE *]	DCN-2458

1.0 PURPOSE

- 1.1 The purpose of this policy is to provide guidance to CAH employees by outlining the steps involved in the conduct of on-site investigations of Cardinal Health's customers to obtain information regarding their potential risk for diversion of regulated drugs.
- 1.2 To be in compliance with the federal Controlled Substances Act and regulations promulgated pursuant to that Act as described in the following sections of the CFR.

- §1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

- §1310.05 Reports.
(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

1. Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.

- 1.3 Notwithstanding the requirements of the CFR, any Memorandum of Understanding with the Drug Enforcement Administration that modifies the requirements of the CFR will take precedence.

2.0 SCOPE

- 2.1 The procedures described in this policy apply when it is determined that an on-site investigation of a DEA-registered customer is necessary to meet the objectives outlined in Section 1.0 above.
- 2.2 The basic procedures outlined in this policy address the retail independent class of pharmacies and should be followed for all pharmacy classes unless otherwise stated within the policy. Unique requirements which pertain to a specific class of pharmacy trade are identified within the policy. Some examples of other classes of pharmacy trade include: retail chain, hospital, long term care, managed care, sterile product pharmacies, ambulatory care surgery centers, practitioner offices, etc.

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3.0 INCLUDED ATTACHMENTS AND FORMS [HYPERLINK \ "Attachment1"] Example Memo
[{ HYPERLINK \ "Attachment1" }

[HYPERLINK \ "Attachment2"] Example Memo
[{ HYPERLINK \ "Attachment2" }

4.0 POLICY

4.1 Definitions

- CAH Cardinal Health, Inc.
- Case An investigation of a customer conducted after a threshold event or after Cardinal learns other information that warrants an on-site investigation to obtain the information necessary to assess the customer's potential risk for diversion.
- Case File An individual file created within the case management system which is unique to a specific case and identified through the customer's DEA number. The file will serve as the investigative log in which all information collected regarding a specific case is to be documented.
- Case Management System A manual or electronic system used by the Director to efficiently and effectively monitor and manage each case.
- CFR Code of Federal Regulations
- CSA Controlled Substances Act
- DEA Drug Enforcement Administration
- Director Director, Supply Chain Integrity and Regulatory Operations or his designee.
Note: the Director is a licensed pharmacist.
- Distrack CAH's warehouse management system which includes information including customer names, inventory, orders, shipments, thresholds, etc.
- Investigator An individual employed by CAH to conduct on-site investigations of customers at the direction of the Director. These individuals are stationed throughout the United States. At times, employees located at the corporate offices will also fill this role.
- Customer Any customer regulated and properly licensed in good standing with the DEA and any other agencies as required by state or federal law for the purchase regulated drugs.
- PBC CAH sales personnel. Acronym for Pharmacy Business Consultant.

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Regulated Drug Controlled substances, List 1 and 2 Chemicals, and other drugs required to be monitored by individual states.

SOM Suspicious Order Monitoring

Suspicious Order A customer's order for a:

- Controlled substance which is of an unusual size, deviates substantially from a normal pattern, or is ordered with unusual frequency;
- List 1 or 2 Chemical which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the listed chemical will be used in violation of the federal Controlled Substances Act; or
- Drug required to be monitored by an individual state which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the drug may be used in violation of state law.

Threshold The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.

Threshold Event An order for a regulated drug which exceeds the threshold set for a specific licensed customer.

Vice-President Vice-President, Anti-Diversion & Supply Chain Integrity & Sr. Regulatory Counsel or his designee. Note: the Vice-President is a licensed pharmacist.

4.2 Receipt & Assignment of Cases

4.2.1 Receipt of Cases

- Threshold events are recorded in the SOM system. A pharmacist evaluates each threshold event according to established procedures and documents a request for an on-site investigation by changing the status of the event in the SOM system to "Site Visit."
- The Director monitors the SOM system and performs the following tasks.
 - Search for all entries carrying a status of "Site Visit" and copies the resulting list to an Excel spreadsheet.
 - Using the information contained in the site visit list, the Director will update the U.S. map maintained in his office to reflect the locations of licensed customers needing an on-site investigation.
- In addition, requests for on-site investigations of licensed customers due to reasons other than suspicious orders are made by the Vice-President and forwarded to the Director. The Director enters these requests into an Excel spreadsheet containing all additional requests.
- The Director shall enter each case into a case management system or

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confirm that a case has already been entered.

4.2.2 Assignment of Cases

- The Director will assign each case to an investigator.
- Field investigators are located throughout the United States and are assigned to regions specified as North, South, East, and West. Each investigator will have the primary responsibility for all cases located within their region of responsibility. The Director will generally assigned cases within a region to the investigator assigned to that region. When needed to expedite a case or to increase efficiency and effectiveness of the conduct of a case, the Director will make assignments to field investigators which may be outside their assigned region.
- Upon making the assignment, the Director shall document the assignment of the case in the case management system and notify the investigator.
- On occasion, cases will be assigned to a QRA Compliance Officer based in one of Cardinal's distribution centers.

4.3 Investigative Process

4.3.1 General Principles

- Investigators are responsible, with the assistance of the Director when necessary, for managing their own time to effectively and efficiently schedule, plan, execute, document, and report each assigned case within established time frames.
- Cases shall be worked and the on-site visit to the licensed customer completed within a goal of 30 days of assignment. A final report shall be completed and submitted to the Director within 10 days of the visit. Time extensions must be approved by the Director. Priority cases may be assigned shorter time frames by the Director.
- Investigators are expected to develop and share resources and individual expertise to achieve the objectives of the entire team.
- Each investigation is divided into four basic parts: (1) initial case preparation; (2) background investigation; (3) site visit; and (4) preparation of reports.
- Each of the four basic parts to the investigation shall be documented by the investigator in the case file.
- The Director shall monitor the progress of cases and provide guidance and direction as necessary to develop and move the case to a successful conclusion.

4.3.2 Initial Case Preparation

- Investigators are responsible for maintaining a current list of open cases assigned to them by the Director.
- Following the general principles, investigators will select the cases for the

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next round of facility visits. This decision process should include the age of the event, priority set by the Director, and proximity of pharmacies to one another.

- Gather and review the information possessed by CAH regarding the case and the licensed customer. Depending on the case and customer, this may include, but is not limited to, information located in the following systems.
 - SOM
 - SCI Repository
 - Hard copy files maintained in the Corporate office
 - Distrack
- Develop a background research plan based upon the information obtained from CAH resources and personal investigative background and instincts. In particular, the investigator should review the following.
 - Licensed customer information
 - Threshold events
 - Customer responses to Questionnaires
 - Previous decisions regarding shipment to the licensed customer.
- Document this case preparation within the appropriate case file.

4.3.3 Background Investigation

- Create a site visit schedule and make travel arrangements.
- Follow through on the research plan to gather and review outside information and/or to verify information contained in CAH records.
- Identify useful internet resources to conduct background and licensure information searches for the pharmacies, their employees, identified local physicians, identified local health care facilities, and obtain geographical information, etc.
- Research, identify and/or verify:
 - any disciplinary actions taken by licensing agencies taken against any of the licenses issued to the facility or to any of the owner/employees of the licensed customer; and
 - any civil or criminal actions documented by federal/state/municipal courts or any other entity which permits access to public records that have been filed against any of the licensed customers, their employees, identified local physicians, or any other person associated with the facility.
- Conduct an Internet search for any evidence that the facility has an Internet presence.
- Useful Internet resources will vary depending on the case itself as well the availability of the Internet site at any given time. Some potentially helpful Internet resources include the following.
 - Google
 - Reverse address and phone directory

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- Location photographs from Google Earth or Yahoo Maps
 - Wikipedia (city information)
 - Global Internet Management (DEA # verification)
 - Secretary of State (Corporate information)
 - Department of Health
 - State Board of Pharmacy
 - ZABA Search (personal information)
- Personal contact with local, state, or federal agencies or law enforcement organizations may occasionally be necessary. Such contact must be approved by the Director.
 - Document this background investigation within the appropriate case file.

4.3.4 Investigator Contacts for On-Site Visits

- Approximately on week prior to an on-site visit, the investigator must communicate with an appropriate representative of the licensed customer to discuss the purpose of the visit and to set a date and approximate time for the visit.
The contact person for the licensed customer will vary depending on the type of facility. For example, the contact person for a retail independent pharmacy is usually the pharmacist-in-charge or the owner of the pharmacy. The contact person for a retail chain pharmacy may be the pharmacist-in-charge, a regional or corporate manager, or a loss prevention manager.
As CAH increases the scope of its anti-diversion program and expands to different types of licensed customers, specific contacts will be identified and a master list established and maintained. It will be responsibility of the investigator to determine the proper contact person for each case.
- The PBC assigned to the licensed customer should also be contacted and provided the opportunity to be present during the visit.

4.3.5 Site Visit

- **Data Collection Worksheets** - Information collected during a site visit should be documented on a data collection worksheet which may be unique to the type of facility being visited. Information collected on the data collection worksheet will serve as the basis for documentation of the visit in the case file.
The data collection worksheet is not all inclusive and should merely be used as a guide to collect uniform data applicable to the licensed customer. Investigators should be observant and are expected to include any additional information obtained which may assist in meeting the objectives identified in Section 1.0 of this procedure.
- **Potential Indicators of Diversion** - Investigators should be particularly alert during the on-site visit to any potential Indicators of diversion. Indicators noted during the visit must be documented in the final data collection worksheet or memo and placed in the appropriate case file. Some indicators of potential diversion include the following.

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- Customers of the licensed customer exhibit drug seeking behaviors.
 - Cars full of pharmacy customers.
 - Pharmacy customers who appear to be from outside the reasonable drawing area for the facility.
 - Evidence of illicit drug use around the facility (e.g., used syringes, empty prescription containers).
 - Mailing materials or other evidence of operation of an Internet pharmacy.
 - High ratio of prescriptions for regulated drugs versus other drugs.
 - High ratio of regulated prescription drug stock to other prescription drug stock.
 - Small or non-existent front end (non-prescription) drug stock.
 - Primarily cash transactions for regulated drug prescriptions.
 - One employee responsible for the ordering, monitoring, and invoicing of products.
 - High number of customers compared to their peers.
 - For practitioner offices: does the practitioners dispense directly to the public?
 - Lack of auditing processes around purchases.
- **Area Scan** - Upon entering the community or immediate area of the licensed customer being visited, investigators should observe and document the surroundings and note any specifics which relate to the business practices, volume of business, and type of business of the licensed customer. These include, but are not limited to, the following:
 - Types and number of health care facilities located within the area.
 - Number and types of medical practices, especially noting those who have characteristically been heavy prescribers of controlled substances, such as, pain clinics, orthopedics, surgeons, oncologists, cancer centers, weight loss clinics, etc.
 - Unusually large numbers of individuals in the general vicinity of a physician's practice or of the facility.
 - General economic condition of the area.
 - **Setting the Tone for the Visit**
 - Investigators have no authority to require compliance with any request. Our ability to look at documents or to obtain information on-site is entirely dependent on the goodwill of the licensed customer. Therefore, it is incumbent on the investigator to enter and approach appropriate personnel and immediately attempt to establish a good rapport with the customer. Our communicated intent should be to better understand the customer's business so that thresholds for regulated drugs can be set appropriately, thereby decreasing the frequency of threshold events.
 - Be prepared to discuss how the SOM system works and attempt to answer any questions regarding our process. If unable to answer a question accurately, advise that you will obtain the information and get back to the customer. Contact the Director for guidance. For questions outside our area of responsibility and knowledge,

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- attempt to have the customer pose the question to their PBC. If unable to do so, the investigator can forward the question to the PBC. If unsure how to proceed, contact the Director for guidance.
- Remember, we are a guest of the licensed customer while in their facility and they may refuse to permit or provide one or more of your requests. The investigator must not threaten or coerce the customer in an attempt to achieve compliance with the request. If there is a refusal which cannot be resolved and it is an important element of our fact gathering, the investigator should advise that the refusal might hamper our ability to effectively help the customer by setting appropriate drug thresholds. If still refused, proceed with the visit to the extent permitted, but document the refusal in the case file.
 - **Interview** - The investigator should attempt to conversationally interview the appropriate personnel representing the licensed customer. The purpose of this interview should include the following.
 - Completing to the extent possible the data collection worksheet for the facility.
 - Obtaining additional information when responses reveal other areas of potential concern.
 - Attempting to resolve any issues which became evident during the initial preparation and background investigation including customer responses to questionnaires.
 - For facilities containing sterile areas, investigators must make the decision if they feel they need to go into the sterile area. Base the decision on criteria such as visibility into the sterile areas.
 - **Tour of the Facility** - A tour of the facility should be requested and should include ALL areas of the facility. Ask for permission to take photographs of the facility.

It is suggested that the investigator obtain photographs of:

 - the front of the prescription department;
 - the front end non-prescription drug section(s);
 - several prescription bays or shelves;
 - back room;
 - any automation; and
 - front of the facility from the outside

Use extreme care if photographs are taken of any indicators of diversion. It might be safer to document the situation in writing in your case notes rather than risk a potential confrontation by taking a photograph. DO NOT put yourself at risk.

Download the digital photographs to the case file and label with the name of the facility.
 - **Requesting Utilization Reports** - If the licensed customer has not provided a recent drug utilization report, investigators should request one. Try to have the report prepared and sent electronically rather than hard copy or fax. Request a drug utilization report with the following

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characteristics.

- Includes all controlled substances by quantity dispensed or administered.
- Includes 6 to 12 months of usage data by month (preferably 12).
- Data comes directly from the facility's computer system.
- Does not include non-controlled drugs unless specifically requested.

Request that the submission include the complete facility name, address, phone number, DEA #, and contact person.

How to Submit

Electronic reports should be emailed to the investigator and forwarded to the appropriate CAH email address indicated below. Be sure that the submission includes the facility information above.

Hard copy reports should be faxed to the investigator's Right Fax and emailed to the appropriate CAH email address indicated below. Be sure that the submission includes the facility information above.

Hard copy reports given to the investigator during the visit should be faxed to 614-652-9631. Be sure that the submission includes the facility information above as well as your contact information.

What to Include

Advise that the utilization report was prompted by a QRA visit and a copy of the results should be provided to the investigator at your email address and to Steve Morse at: steve.morse@cardinalhealth.com.

CAH email Addresses

Retail Independents: GMB-QRA-Anti-Diversion
Managed Care: GMB-QRA-AD-Managed Care

4.3.6 Final Report

- Prior to preparing the final report, the investigator must research and confirm to the extent possible any additional information received during the on-site visit to the licensed customer.
- The investigator shall analyze the information collected and documented in the case file and formulate a recommendation for presentation to the Director. At a minimum, the recommendation should indicate whether the investigator believes:
 - the facility does not at this time represent a significant risk for diversion; OR
 - the facility represents a significant risk for diversion.
- The investigator shall prepare a final report in the form of a memo (see [[HYPERLINK \ "Attachment1" \ "Attachment1"](#)] and [[HYPERLINK \ "Attachment2" \ "Attachment2"](#)]).
- At a minimum, the memo shall contain the name, DEA number, city, and state of the facility in the subject line. The body of the memo shall contain:

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- an opening paragraph providing the date of the visit and the principle individuals participating in the visit;
- followed by a summary of the findings in bullet point form, both positive and negative, considered in making the recommendation;
- the recommendation.

Findings bulleted in the final report should consist of a summary of the findings documented in the case file. Details should remain in the case file for review unless necessary to provide a proper perspective for the recommendation.

4.4 Analysis & Decisions

- 4.4.1** The Director shall conduct a thorough, final review of each case and make a determination whether the case is complete and provides the information necessary to support a recommendation of whether or not a significant risk for diversion exists. The investigator will be contacted if necessary to clarify issues or to address questions regarding the case, the reports, and the recommendation.
- 4.4.2** The Director shall document on the final report an approval of the recommendation of the investigator. In the event that the Director comes to a different recommendation, documentation shall be made as an addendum to the final report with justification for the different recommendation.
- 4.4.3** Once a final recommendation has been made, a decision regarding whether to continue to supply regulated drugs to the customer must be made and appropriate follow-up steps initiated.
- A decision to continue the sale of regulated drugs to the customer requires an evaluation of the customer's threshold limits for regulated drugs and adjustments when supported by findings documented in the case. The Director, or another pharmacist, shall conduct such an evaluation and adjust thresholds appropriately.
 - A decision to discontinue the sale of regulated drugs to the customer requires the termination of the customer from the Cardinal Health system and notification to state and federal regulatory bodies.

4.5 Miscellaneous Odds & Ends

- 4.5.1** Upon the completion of a case, the Director will see that the following actions are taken.
- A copy of the final, approved report, any case notes, related documents, and photos (if any) are placed in the SCI Repository.
 - If applicable, any SOM system records for the customer indicating a status of "Site Visit" are changed to a status of "Closed."

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5.0 APPLICABLE None
 DOCUMENTS

Approvals on file in the Pharmaceutical Distribution Document Center			Owner: Steve Morse
Approvers: Michael Mone'			Doc Center: Jason Paul Snouffer
Change History			
DCN-2458	11/05/09	Updated procedure to conform to existing Cardinal Health practices and to conform to current Pharmaceutical Distribution restructuring. Changed document owner from Chris Forst to Steve Morse. Initial release of new procedure, HSCSQRA-CAD-C008.	
DCN-2313	12/22/08		

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Attachment 1



Cardinal Health
7000 Cardinal Place
Dublin OH 43017

Date 7/18/08
To File
From Vince Moellering
Subject Morse's Magnificent Pharmacy AM0284769
Austin, TX

This pharmacy was visited on 7/08/08 by Vince Moellering, CAH. Met with manager of the pharmacy, Mr. Steve Morse.

Findings

- Location/Area –Located in a large, five story medical building//Austin Hospital is across the street with many businesses and restaurants in the area//inside the medical building are two pain clinics, 2 oncology practices, several GP physicians with some of them treating mostly worker's compensation patients = large number of pain scripts, one dialysis center and no weight loss centers//Austin Hospital has a large oncology center
- Practitioners identified by the pharmacy as their primary prescribers of controlled medications, all held active, current medical licenses to prescribe said medications, with current DEA registration numbers//Mr. Morse identified one physician whom he opined as a heavy prescriber of Oxycontin and he has turned away some the physician's patients as they appeared in good health and young. Mr. Morse has spoken with this older physician and informed him that he would accept his patient's prescriptions at his discretion //I conducted a search of the Texas Board of Medical Licensure, Google and DEA websites with no negative finds on this physician
- Dispensing data was provided by the pharmacy and mailed to CAH QRA.
- No evidence of mail service or internet prescription sales
- The pharmacy had a small front end with insignificant OTC business
- The pharmacy had significant non-controlled prescription business
- Moderate amount of walk-in traffic was observed during the visit//mixed base of customers
- Photographs were taken of the pharmacy but were not recovered from the camera.

Recommendation

The visit to this pharmacy resulting in the findings above, support the determination at this time that the pharmacy does not represent a significant risk for diversion.

Reviewed & Approved: SM

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Attachment 2



Cardinal Health
7000 Cardinal Place
Dublin OH 43017

Date 7/18/08
To File
From Vince Moellering
Subject Wonderful Care Pharmacy BW3768491
Burning Blanket, TX

This pharmacy was visited on 7/10/08 by Vince Moellering, CAH. Met with PIC of the pharmacy, Mr. Imtha Owner and Steve Morse, CAH PBC

Findings

- Location/Area –Located in a strip mall, surrounding by many stores on a busy four lane street, next to an intersection//Only 10% of the pharmacy business is from walk ins and prescribing physicians in the area//pharmacy delivers to a large number of assisted living facilities (ALF) in the San Diego area//bubble packs all medications at the pharmacy for delivery to these facilities//CAH distract lists this pharmacy as a managed care, closed door pharmacy but there is also some retail business
- Dispensing data was not requested
- Clonazepam continues to be a largely prescribed drug at the ALFs.
- No evidence of mail service or internet prescription sales//majority of business is delivered to ALFs
- The pharmacy had insignificant business dispensing OTC drugs
- Store was closed at the time of the visit, which was at 7:00 a.m.
- Mr. Owner declined permission for photographs to be taken of the store

Recommendation

The visit to this pharmacy resulting in the findings above, support the determination at this time that the pharmacy does not represent a significant risk for diversion.

Reviewed & Approved: SM

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